



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General  
Office of Audit Services

Region VII  
601 East 12th Street  
Room 284A  
Kansas City, Missouri 64106

June 24, 2003

Report Number A-07-03-04014

Kevin W. Concannon  
Director  
Department of Human Services Director's Office  
Hoover State Office Building, 5<sup>th</sup> Floor  
Des Moines, IA 50319

Dear Mr. Concannon:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Service's (OAS) final report entitled "*Audit of the Medicaid Drug Rebate Program in Iowa.*"

The HHS action official named below will make final determination as to actions taken on all matters reported. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the worldwide web at <http://oig.hhs.gov>. To facilitate identification, please refer to Report Number A-07-03-04014 in all correspondence relating to this report.

Sincerely,

A handwritten signature in black ink, which appears to read "James P. Aasmundstad", is written over a horizontal line.

James P. Aasmundstad  
Regional Inspector General  
for Audit Services

**Direct Reply to HHS Action Official:**

Mr. Joe Tilghman  
Centers for Medicare and Medicaid Services  
Regional Administrator, Region VII  
601 East 12<sup>th</sup> Street, Room 235  
Kansas City, Missouri 64106

Enclosures—As stated

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**AUDIT OF THE MEDICAID DRUG  
REBATE PROGRAM IN IOWA**



**JUNE 2003  
A-07-03-04014**

# ***Office of Inspector General***

<http://oig.hhs.gov/>

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## **OAS FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed as well as other conclusions and recommendations in this report represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the awarding agency will make final determination on these matters.





## DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 24, 2003

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601 East 12th Street  
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Report Number: A-07-03-04014

Mr. Kevin W. Concannon, Director  
Department of Human Services Director's Office  
Hoover State Office Building, 5<sup>th</sup> Floor  
Des Moines, Iowa 50319

Dear Mr. Concannon:

This final report provides you with the results of our *Audit of the Medicaid Drug Rebate Program in Iowa*.

### EXECUTIVE SUMMARY

#### OBJECTIVE

The audit objective was to evaluate whether the Iowa Department of Human Services (DHS) had established adequate accountability and internal controls over the Medicaid drug rebate program.

#### FINDINGS

We found that the DHS lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by Federal rules and regulations. Areas that lacked sufficient internal controls included:

- Recording accounts receivable.
- Form CMS 64.9R and general ledger reconciliation.
- Reporting rebates received.
- Dispute resolution.
- Interest accrual, collection and reporting.
- Records retention.

These issues occurred because the DHS did not develop or follow adequate policies and procedures with regard to the drug rebate program and its management by Affiliated Computer Services, Inc. (ACS), a company DHS contracted with to administer the drug rebate program. Federal regulations require effective control over and accountability for all funds, property and other assets; and the establishment of minimum records retention requirements. In addition, the rebate agreements between the Centers for Medicare and Medicaid Services (CMS) and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates, and the use of the State's hearing mechanism

to resolve disputes. Also, the State Medicaid Manual requires interest revenue to be reported on the Form CMS 64 Summary Sheet.

Our review showed that drug rebate receivables were perpetually understated and it is likely that the DHS did not receive all drug rebates and interest on disputed or late rebate payments due from manufacturers. In addition, the DHS did not have reasonable assurance that drug rebate balances and collections reported to CMS were accurate. Moreover, the lack of sufficient internal controls increased the risk for fraud, waste, or abuse of drug rebate program funds.

## **RECOMMENDATIONS**

We recommend that the DHS develop and follow policies and procedures that include:

- Establishing a general ledger accounts receivable account for drug rebates.
- Reconciling the general ledger account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.
- Reporting rebate collections in the proper time period.
- Making use of the State's hearing mechanism to resolve disputes after 60 days.
- Estimating and accruing interest on all overdue rebate balances.
- Properly reporting interest collections on the Form CMS 64 Summary Sheet.
- Ensuring that records are kept for an appropriate period of time.

The DHS generally disagreed with our findings and recommendations. Following the recommendations section of the report, we summarized DHS' response to each finding and included our comments. The complete DHS response is included in Appendix A.

## **INTRODUCTION**

### **BACKGROUND**

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the state(s). The legislation was effective January 1, 1991. The CMS also issued release memorandums to state agencies and manufacturers throughout the history of the rebate program to give guidance related to the Medicaid drug rebate program.

A manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. The manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS provides the unit rebate amount (URA) information to the State agency on a quarterly computer tape. However, the CMS tape may contain a \$0 URA if the pricing information was not provided timely, or if the computed URA has a 50 percent variance from the previous quarter. In instances of a \$0 URA, the State agency is instructed to invoice the units and the manufacturer is required to calculate the URA and remit the appropriate amount to the State agency. In addition, the manufacturers can change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement.

Each State agency is required to maintain drug utilization data for total units dispensed, by manufacturer, for each covered drug. That number is applied to the URA to determine the actual rebate amount due from each manufacturer. Each State agency is required to provide drug utilization data to the manufacturer and CMS on a quarterly basis. Approximately 56,000 National Drug Codes (NDC) are available under the program.

The manufacturer has 38 days to remit payment from the date an invoice is postmarked. The manufacturers provide the State agency with a Reconciliation of State Invoice detailing their payment by each NDC. A manufacturer can dispute utilization data that is believed to be erroneous, but they are required to pay the undisputed portion by the due date. If the manufacturer and the State agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the State agency by the due date. If the State agency and the manufacturer are not able to resolve the discrepancy within 60 days, the State agency must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

The manufacturer is required to calculate and remit interest for disputed rebates when settlement is made in favor of the State. Governmental Accounting and Financial Reporting Standards require states to calculate and accrue a reasonable estimate of the interest owed. Tracking interest owed to the State agency is required by CMS.

Each State agency reports, on a quarterly basis, rebate collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the Federal share of these expenditures. Specifically, states report rebates invoiced in the current quarter, rebates received during the current quarter, and uncollected rebate balances for the current and prior quarters on the Form CMS 64.9R.

The DHS reported to CMS an uncollected rebate balance of \$17,161,076 on the CMS 64.9R as of June 30, 2002. Although the DHS reported no uncollected balances over 90 days old on the report, we determined that at least \$2.1 million remained uncollected for billings over 90 days old.

## **OBJECTIVE, SCOPE AND METHODOLOGY**

### ***Objectives***

The audit objective was to evaluate whether the DHS had established adequate accountability and internal controls over the Medicaid drug rebate program.

### ***Scope***

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of the DHS. We also interviewed DHS staff to understand how the Medicaid drug rebate program has operated since 1991.

### ***Methodology***

To accomplish our objective, we reviewed the applicable Federal laws, regulations, and requirements including sections 1903 and 1927 of the Social Security Act, the Omnibus Budget Reconciliation Act of 1990 and the Office of Management and Budget Circular A-87.

We examined copies of the Form CMS 64.9R reports for the period July 1, 2001 through June 30, 2002 submitted to CMS by the State of Iowa. We obtained and reviewed drug rebate accounts receivable records. Finally, we interviewed ACS staff that performed functions related to the drug rebate program.

Our fieldwork was conducted at DHS and ACS offices in Des Moines, Iowa during November and December 2002, and continued in the Office of Audit Services field office in Kansas City, Missouri through March 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

## **FINDINGS AND RECOMMENDATIONS**

We determined the DHS lacked sufficient internal controls with regard to the Medicaid drug rebate program as required by federal rules and regulations. Areas that lacked sufficient internal controls included:

- Recording accounts receivable.
- Form CMS 64.9R and general ledger reconciliation.
- Reporting rebates received.
- Dispute resolution.
- Interest accrual, collection and reporting.
- Records retention.

## INTERNAL CONTROLS

### Accounts Receivable

While the DHS maintained a general ledger account for drug rebate collections, neither the DHS nor its contractor maintained a general ledger accounts receivable control account for uncollected rebate balances as required. Drug rebates are “other assets” to the State that should be accounted for properly.

Title 45, sec. 74.21, paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for “Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes.” Additionally, generally accepted accounting principles (GAAP) require the use of a general ledger. The National Council on Governmental Accounting (NCGA)<sup>1</sup> issued *Statement 1, Governmental Accounting and Financial Reporting Principles*. It states in part,

*A governmental accounting system must make it possible both: (a) to present fairly and with full disclosure the financial position and results of financial operations of the funds and account groups of the governmental unit in conformity with generally accepted accounting principles; and (b) to determine and demonstrate compliance with finance-related legal and contractual provisions.*

Because there was no general ledger for accounts receivable to reconcile to the subsidiary ledger, the DHS had no reasonable assurance that rebate receivables were accurate or effectively safeguarded. In fact, the receivable balance reported for June 30, 2002 on the Form CMS 64.9R was \$17,161,076 and did not agree with the ACS receivable balance of \$13,369,942. Moreover, the DHS did not recognize any Medicaid drug receivable amount in its accounting system. As a result of this accounting weakness, rebate funds were subject to potential waste, fraud, and abuse.

### Form CMS 64.9R and General Ledger Reconciliation

The DHS did not perform a reconciliation to verify the accuracy of the uncollected rebate balances and collections reported on the Form CMS 64.9R as required by 45 CFR 74.21 (b)(3). Without a general ledger control account, routine reconciliations could not be performed.

Without routine reconciliations, the DHS did not have reasonable assurance that receivables were adequately safeguarded or that drug rebate information reported to CMS was accurate.

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<sup>1</sup> The Governmental Accounting Standards Board (GASB) establishes standards for activities and transactions of State and local governmental entities. Its pronouncements are authoritative for State and local governmental entities. Following the jurisdictional approach discussed in the GASB Codification of Governmental Accounting and Financial Reporting Standards, the hierarchy of GAAP for governmental entities begins with GASB pronouncements and all pronouncements of the NCGA acknowledged as applicable by the GASB.

**Reporting Cash Receipts**

Drug rebate collections on the Form CMS 64.9R were not reported accurately. Government Accounting and Financial Reporting standards require the States to use the modified accrual method and to accrue revenue when it is measurable and available.

There was a timing difference between DHS' reporting of collections on the Form CMS 64.9R and ACS collections as recorded in subsidiary records. Specifically, DHS did not report collections by ACS for the final month of a quarter on the Form CMS 64.9R for that quarter. Rather, they reported those collections in the following quarter.

The ACS recorded receipts in the month that collections were received and applied to subsidiary accounts. Rebate checks were deposited in a DHS account managed by ACS and a single check was sent to DHS the following month for the previous month collections. For example, DHS received a check for \$2,977,860 from ACS, for June collections, dated July 10, 2002 which could have been reported on Form CMS 64.9R for the quarter ending June 30, 2002. The DHS did not report June collections until the September 30, 2002 Form CMS 64.9R resulting in a \$3 million overstatement of receivables and a \$3 million understatement of collections for the June quarter.

**Dispute Resolution**

The DHS did not utilize state hearings to resolve disputes as required by the rebate agreement. Specifically, the rebate agreement requires that the State and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program.

While the DHS did not use the State's hearing mechanism, they did contact manufacturers directly to resolve disputes. In addition, the DHS used the Dispute Resolution Program (DRP) meetings to resolve disputes with those manufacturers who attended. Because manufacturers were not required to attend DRP meetings, and there were no other sanctions provided in the regulations, there were no incentives for the manufacturers to resolve claims. The DHS did not actively pursue disputes that were not adjudicated during DRP meetings or through direct contact. Direct contact generally consisted of a notification letter and perhaps a follow-up letter. We believe that the DHS could increase collections by offering manufacturers access to the State's hearing mechanism.

**Interest on Late, Disputed, and Unpaid Rebates**

The DHS did not have adequate procedures to accrue interest for late, disputed or unpaid rebate payments as required by Federal rules and regulations.

According to the rebate agreements between the manufacturers and CMS, required by section 1927 of the Social Security Act, manufacturers are required to pay interest on disputed or unpaid amounts and late rebate payments. The interest rate according to section 1903 (d)(5) of the Social Security Act is “based on the yield of the weekly 90-day Treasury bill auction rates” during such period. Section V, paragraph (b) of the rebate agreement states:

*If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.*

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers’ responsibility to calculate and pay interest for applicable rebate invoices and the State’s responsibility to track collections and report those amounts to CMS. In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State. Finally, Governmental Accounting and Financial Reporting standards require states to accrue revenue (interest) when it is measurable (a reasonable estimate) and available.

The DHS did not calculate and accrue interest for late or disputed payments as required by Federal regulations, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid. Moreover, they did not make significant efforts to collect from manufacturers that did not voluntarily remit interest owed.

Because the DHS did not accrue revenue as required, the drug rebate receivables were perpetually understated, and it is likely that the DHS did not receive interest owed by the manufacturers.

**Interest Reporting**

The DHS did not establish procedures to report interest received as required by Federal rules and regulations, but instead, included interest as a rebate collection on Form CMS 64.9R. According to the State Medicaid Manual, interest should be reported separately on the Form 64 summary sheet. Reporting interest revenue on Form CMS 64.9R caused the receivables to be understated by \$6,271 for the fiscal year ended September 30, 2002.

As a result, drug rebate collections were overstated and the receivable balance was understated for that period, as were all other quarterly results that were reported using this methodology.

### **Records Retention**

The DHS did not adequately retain records pertaining to the Medicaid drug rebate program as required.

According to 45 CFR 92.42 (b)(3) records for a cooperative agreement (continued or renewed quarterly) are required to be kept three years from:

*...the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year.*

Furthermore, the “Best Practices for Dispute Resolution” provided by CMS states that:

*States should maintain completed and accurate records of all checks received, unit adjustments, write-offs, resolutions, interest paid, outstanding balances, and contacts with manufacturers. The lack of adequate and accurate documentation prolongs the process of rebate payment, as well as the process of resolution of disputes.... records should be maintained indefinitely at this point.*

The DHS’ current contractor, ACS, did not pursue the collection of receivables totaling \$547,456 for the period January 1, 1993 through June 30, 1997. The ACS inherited responsibility for these receivables from the previous fiscal agent and ACS personnel determined that the records supporting these receivables were missing or incomplete. The missing information is required to re-start the dispute resolution process.

The records were not maintained because the DHS did not have effective policies and procedures to ensure that the contractors maintained proper records. As a result, the DHS may not have received all drug rebates due from manufacturers.

### **RECOMMENDATIONS**

We recommend that the DHS develop and follow policies and procedures that include:

- Establishing a general ledger accounts receivable account for drug rebates.
- Reconciling the general ledger account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.
- Reporting rebate collections in the proper time period.
- Making use of the State’s hearing mechanism to resolve disputes after 60 days.
- Estimating and accruing interest on all overdue rebate balances.
- Properly reporting interest collections on the Form CMS 64 Summary Sheet.
- Ensuring that records are kept for an appropriate period of time.

## **AUDITEE RESPONSE AND OIG COMMENTS**

The DHS did not concur with all of our findings and recommendations. Their comments are summarized below and included in their entirety as Appendix A.

### **1) Establishing a general ledger accounts receivable account for drug rebates.**

#### **Auditee Response:**

The DHS did not concur with our finding. According to the DHS, a contractor maintained a general ledger control account for the drug rebate program on behalf of the department. They claimed it would have been duplicative for the DHS to maintain a general ledger account since the information comes from the contractor.

The DHS asserted that the OIG draft report contained no findings indicating any deficiencies in the ACS accounting system, including its accounts receivable for uncollected rebates.

#### **OIG Comments:**

The DHS reported to CMS an uncollected rebate balance of \$17 million as of June 30, 2002. The State did not recognize any uncollected rebate balance in the State's accounting system. While ACS did maintain a detailed subsidiary ledger of drug rebate receivables, this subsidiary accounting system was not a general ledger because it did not employ dual entry accounting.

Without a general ledger control account for the rebate accounts receivable, the DHS did not have reasonable assurance that balances in the subsidiary ledgers and the rebate balances reported to CMS were correct. For example, a posting error to the subsidiary ledger would not be detected. Moreover, an unauthorized write-off of an account balance by the contractor could be processed without detection.

As reported in our draft report, ACS administered the drug rebate program under contract with the DHS and these internal control weaknesses occurred because the DHS did not develop adequate policies and procedures with regard to the drug rebate program and its management by ACS.

After we received the DHS' response to our draft report, dated April 25, 2003, we requested a meeting to discuss the findings in more detail. Specifically, we clarified to DHS officials that the draft report referred to a lack of a general ledger accounts receivable control account at DHS and ACS. During this meeting, we agreed to allow DHS to amend their response to the draft report to more fully describe their position.

However, the amended response still indicated that the accounts receivable control account for uncollected rebate balances maintained by ACS serves as the department's detailed general ledger account for the drug rebate program and that the OIG draft report contained no findings indicating any deficiencies in ACS' accounting system.

To further clarify our position, we changed the final report to read that *neither* the State *nor* ACS maintained a general ledger accounts receivable control account to account for uncollected rebate balances as required (*italics indicates change*).

In summary, we believe that a \$17 million receivable balance requires stronger controls to properly safeguard the receivables. The DHS or the contractor should establish and maintain an accounts receivable balance in a dual entry accounting system to properly account for the uncollected drug rebates.

**2) Reconciling the general ledger account to the subsidiary ledger/records and to the Form CMS 64.9R.**

**Auditee Response:**

The DHS indicated that they continue to pursue additional reconciliation procedures that can be implemented to enhance controls and assist in ensuring accuracy of reported receivables. However, they indicated that ACS has a general ledger control account for tracking uncollected rebate balances and a reconciliation between ACS and DHS records would be duplicative because DHS would rely on ACS' records. Moreover, they asserted that their assurances that the rebates receivables maintained by ACS are accurate and effectively safeguarded are contained in the contract between DHS and ACS and involves continual review of ACS' internal controls and procedures and audit of records.

**OIG Comments:**

We commend the DHS for pursuing additional reconciliation procedures. To ensure the accuracy of the uncollected rebate balance reported to CMS, the DHS should reconcile the uncollected rebate figure on the Form CMS 64.9R to the contractor's subsidiary ledger.

As stated above, the drug rebate receivable balance reported for June 30, 2002 on the Form CMS 64.9R was \$17,161,076 and did not agree with the ACS receivable balance of \$13,369,942. While a timing difference could explain this difference, the absence of a quarterly reconciliation procedure to document the cause of this difference is a significant deficiency that needs to be addressed.

Moreover, we believe that to adequately safeguard the accounts receivable, the DHS or the contractor needs a dual entry accounting system to establish a general ledger accounts receivable control account. The general ledger control account needs to be routinely reconciled to the detailed activity in the subsidiary ledger. Currently, the DHS cannot perform an adequate reconciliation of the uncollected rebate balance between the general ledger and the subsidiary accounting records because the uncollected rebate balance is maintained in a single subsidiary system. In short, there is no general ledger account to reconcile with the subsidiary accounting records.

While the DHS indicated they have assurances that rebate receivables maintained by ACS are accurate and effectively safeguarded because of a contract provision and constant contract monitoring, DHS' monitoring of the contractor did not ensure proper reconciliations of drug rebate receivables. Moreover, DHS' monitoring did not prevent the previous contractor from losing records associated with receivables totaling \$547,000.

**3) Reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.**

**4) Reporting rebate collections in the proper time period.**

**Auditee Response:**

In terms of reconciling the Form CMS 64.9R with ACS' records, the DHS indicated that it can be done by accounting for the timing difference between ACS' records and the collection figures reported to CMS. In addition, the DHS explained that cash receipts were reconciled on the last day of the month by the contractor, but payment to DHS was not made until the following month. Therefore, cash collections reported on the Form CMS 64.9R were one month behind actual collections. They stated that CMS was aware of their practice and has accepted it.

**OIG Comments:**

At a minimum, the DHS should develop a reconciliation procedure to verify that the amount reported to CMS for drug rebate collections on the Form CMS 64.9R is supported by ACS' accounting records. This reconciliation should take into account the timing difference. While the DHS' response indicated that this reconciliation could be done, the DHS did not indicate that they plan on establishing such a procedure.

Given the complexity of the issues that caused the timing differences, we acknowledge there is no simple solution to eliminate the timing difference. We suggest that the DHS explore options for eliminating this timing difference without sacrificing the contractor's current internal controls over cash receipts.

**5) Making use of the State's hearing mechanism to resolve disputes after 60 days.**

**Auditee Response:**

The DHS asserted that the State's hearing process was not required for dispute resolution because states are not a direct party to the rebate agreement and they are unaware of any authoritative requirement that they use hearings to solve disputes. Furthermore, they contended that using a hearing mechanism would require them to provide documentation of every prescription related to the dispute and may not be cost effective. The DHS stated that their contractor has pursued only the top 25 manufacturers and has been successful by attending DRP meetings and sending contact letters.

**OIG Comments:**

We disagree with the DHS' position that the states are not a party to the rebate agreement. Specifically, the Social Security Act, section 1927, states:

*In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer)....*

The rebate agreement states that in the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program. Some manufacturers interpret these provisions to mean the disputes are automatically resolved in their favor if states do not formally respond to their written disputes within 60 days, or offer a hearing. Therefore, we believe, at a minimum, the DHS should offer the State's hearing mechanism to settle disputes when the State has received a written notice of dispute from a manufacturer.

**6) Estimating and accruing interest on all overdue rebate balances.****Auditee Response:**

The DHS contended that it is unaware of any authoritative requirement that the State either calculate or recalculate the interest amount; interest calculation is the manufacturer's responsibility. The DHS indicated that it would apply a \$50 tolerance when they determine that administrative costs to recover interest owed by a drug labeler exceeds the interest due.

**OIG Comments:**

The DHS did not respond directly to our recommendation regarding the accrual of interest on overdue rebate balances. Governmental Accounting and Financial Reporting standards require accruing interest when it is measurable and available. Accordingly, the DHS should estimate, accrue, and re-bill if necessary, interest on late or unpaid rebate amounts that are not in dispute as well as interest on disputed amounts that have been resolved in the State's favor.

We believe the DHS should not accept an interest payment from a manufacturer as payment in full without determining the accuracy of the payment. Without comparing the amount paid to the amount due, the DHS does not have reasonable assurance that the manufacturer's interest payment complied with the terms of the rebate agreement.

Therefore, we suggest that the DHS consider the costs and benefits associated with making the necessary changes to its drug rebate system to accrue interest.

**7) Properly reporting interest collections on the Form CMS 64 Summary Sheet.**

**Auditee Response:**

The DHS concurred with our finding and has implemented procedures to separate the interest portion of collections and has begun reporting that amount on the Form CMS 64.9R Summary Sheet.

**8) Ensuring that records are kept for an appropriate period of time.**

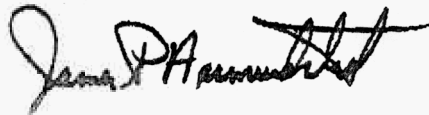
**Auditee Response:**

The DHS agreed that a previous contractor had not adequately maintained drug rebate records and that the current contractor was unable to reconstruct them. They maintained that \$547,456 was a small part of the program and it would not have been cost effective to pursue those claims. Furthermore, they stated that the current contractor has maintained accurate records and that we did not find any deficiencies in their records during our audit. The DHS requested confirmation whether all or part of this amount may be written-off.

**OIG Comments:**

To ensure that the program does not suffer another loss, DHS should establish written policies and procedures requiring the maintenance of critical drug rebate records. As far as write-offs of any drug rebate amounts, we suggest that DHS follow the CMS guidance promulgated in the program releases.

Sincerely,

A handwritten signature in black ink, appearing to read "James P. Aasmundstad", with a stylized flourish at the end.

James P. Aasmundstad  
Regional Inspector General  
for Audit Services



# STATE OF IOWA

THOMAS J. VILSACK, GOVERNOR  
SALLY J. PEDERSON, LT. GOVERNOR

JUN 11 2003

DEPARTMENT OF HUMAN SERVICES  
KEVIN W. CONCANNON, DIRECTOR

James P. Aasmundstad, Regional Inspector for Audit Services  
HHS/OIG/OAS, Region VII  
Room 284A  
601 East 12<sup>th</sup> Street  
Kansas City, MO 64106

RE: AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN IOWA  
AUDIT REPORT CIN: A-07-03-04014

Dear Mr. Aasmundstad:

Based on a meeting with OIG Senior Auditor Randy Parker on May 27, 2003, to discuss the Iowa Department of Human Services' (DHS) initial response dated April 25, 2003, to the draft report from OIG dated March 31, 2003, concerning Iowa's Medicaid Drug Rebate Program, the department has revised responses to two of the findings to more fully describe Iowa's position on these issues.

The enclosed includes changes to our responses to the following two findings and should be considered the department's final response to the draft audit report.

- (1) Finding: Accounts Receivable (Pages 4-5 from the draft OIG report and pages 2-3 from the initial DHS response).
- (2) Finding: Form CMS 64.9R and General Ledger Reconciliation (Page 5 from the draft OIG report and pages 3-4 from the initial DHS response).

Questions about the attached response can be addressed to:

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Sincerely,

A handwritten signature in black ink that reads "Kevin W. Concannon".  
Kevin W. Concannon  
Director

**AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN IOWA**  
**AUDIT REPORT CIN: A-07-03-04014**  
**Comments from Iowa Department of Human Services (Revised June 11, 2003)**

**BACKGROUND**

The Omnibus Budget Reconciliation Act of 1990 which established the Medicaid drug rebate program included provisions specifying certain requirements on the parts of HHS, state Medicaid agencies, and drug manufacturers. As with any legislation whether federal or state, many details concerning the actual day-to-day operations of the program were left to be addressed through subsequent mechanisms. Most federal programs rely on federal regulations and directions from the administering agency to clarify policies and procedures not specifically addressed in the underlying legislation. Directions may take various forms ranging from Program Instructions (PI's) having the same force and effect as regulations, to non-binding Information Memorandums (IM's).

Since the implementation of the Medicaid drug rebate program in January 1991, no formal regulations concerning the program have been issued by HHS. Instead, HHS has developed and maintained both a *Medicaid Drug Rebate Operational Training Guide* as well as a *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program* to address the daily operations of the program and procedures for resolving disputes between manufacturers and state Medicaid agencies. While guides can be useful tools, they lack the authority of regulations.

Page A3 of the *Medicaid Drug Rebate Operational Training Guide* states "NOTE: This Medicaid Drug Rebate Operational Training Guide is intended for the use of the labeler and state staff involved in the daily operational process of the drug rebate program. The guide is intended as **guidance** [emphasis added]; it is not intended as a revision or modification of the requirements set forth in section 1927 of the Act, the Rebate Agreement, program releases, or any regulations. Likewise, a letter dated December 27, 1999, accompanying the *Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program*, stated that this guide "represents a compilation of **suggested** [emphasis added] steps for HCFA, states, and manufacturers to prevent disputes from arising as well as to facilitate the process of dispute resolution." Consequently, neither state Medicaid agencies nor drug manufacturers are legally bound by any provisions of the guides which exceed the statutory provisions of the Omnibus Budget Reconciliation Act of 1990.

The absence of regulations for the drug rebate program, coupled with the lack of any previous federal review of the program for over 11 years prior to the audit resulting in this report, may have significantly contributed to the nature of some of the findings. Of particular concern is the lack of restrictions on the ability of drug manufacturers to recalculate unit rebate amounts or to dispute claims for an indefinite time. A related concern is the lack of federal authority regarding enforcement to conclude dispute resolutions. Lacking federal authority, states have little recourse in compelling drug manufacturers to settle disputed claims other than through civil litigation.

From July 1, 1992 through June 30, 2002, DHS, through its contracted agents, collected drug rebates totaling over \$280 million. As stated in the report's Executive Summary, approximately 56,000 National Drug Codes (NDC) are presently available under the program. Given the

magnitude of the funds and the numbers of drug manufacturers and drug codes involved, the Medicaid drug rebate program presents a number of challenges.

DHS has utilized two contractors to manage the drug rebate program since its implementation in Iowa. Unisys Services, Inc. provided services from January 1991 until June 30, 1997. Consultec, now known as Affiliated Computer Services, Inc. (ACS), became responsible for managing the drug rebate program effective July 1, 1997, and has done so since that time through the present. A lack of cooperation on the part of Unisys in providing records during the transition forced ACS to reconstruct previous drug rebate activity by working with the drug manufacturers when developing its database for the rebate program. This was a time-consuming task given the number of transactions, both invoices and receipts, involved. The transition process diverted ACS resources that would have preferably been used to pursue outstanding claims remaining from the time period when Unisys managed the drug rebate program.

## FINDINGS AND RECOMMENDATIONS

### *Finding: Accounts Receivable*

The State did not maintain a general ledger accounts receivable control account to account for uncollected rebate balances as required. Drug rebates are “other assets” to the State that should be accounted for properly.

Title 45 sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for “Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes.” Additionally, generally accepted accounting principles (GAAP) require the use of a general ledger. The National Council on Governmental Accounting (NCGA)<sup>1</sup> issued *Statement 1, Governmental Accounting and Financial Reporting Principles*. It states in part,

“A governmental accounting system must make it possible both: (a) to present fairly and with full disclosure the financial position and results of financial operations of the funds and account groups of the governmental unit in conformity with generally accepted accounting principles; and (b) to determine and demonstrate compliance with finance-related legal and contractual provisions.”

Because there was no general ledger for accounts receivable to reconcile to the subsidiary ledger, the DHS had no reasonable assurance that rebate receivables were accurate or effectively safeguarded. In fact, the receivable balance reported for June 30, 2002 on the Form CMS 64.9R

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<sup>1</sup> The Governmental Accounting Standards Board (GASB) establishes standards for activities and transactions of State and local governmental entities. Its pronouncements are authoritative for State and local governmental entities. Following the jurisdictional approach discussed in the GASB Codification of Governmental Accounting and Financial Reporting Standards, the hierarchy of GAAP for governmental entities begins with GASB pronouncements and all pronouncements of the NCGA acknowledged as applicable by the GASB.

was \$17,161,076 and did not agree with the ACS receivable balance of \$13,369,942. As a result of this accounting weakness, rebate funds were subject to potential waste, fraud, and abuse.

*Recommendation.*

Establish a general ledger accounts receivable account for drug rebates.

*Response.*

The official accounting system for the State of Iowa is the Iowa Financial Accounting System (IFAS). This system uses a modified accrual basis of accounting with revenues recognized when measurable and available. The Iowa Department of Human Services (DHS) uses the IFAS system. DHS also utilizes a separate general ledger for each of its appropriation units that records information in addition to the IFAS system, including related receivables and payables. DHS records Medicaid activity in the Medical Assistance appropriation unit general ledger. DHS records pharmaceutical costs when providers are paid and drug rebate revenues when received from the fiscal agent, or on a cash basis. The federal share of the pharmaceutical costs are recognized when paid to the provider and the federal share of drug rebates are recognized when received from the state's Medicaid fiscal agent, Affiliated Computer Services Inc. (ACS).

The state does maintain an accounts receivable control account. However, the account is maintained, in detail, by the state's fiscal agent, ACS. Under current procedures, only totals are recorded in the state's records. Requiring the department to maintain a separate general ledger control account for uncollected rebate balances other than that maintained by ACS, would be duplicative and serve no meaningful purpose.

Maintaining such an account would require recording all of the transactions handled by ACS in the DHS ledger and would simply restate the information from the ACS account. Establishing and maintaining a separate DHS account would provide no additional protection against potential waste, fraud or abuse. DHS's assurances that the rebate receivables maintained by ACS are accurate and effectively safeguarded are contained in the contract between DHS and ACS. The contract executed between DHS and ACS provides that: "The contractor (ACS) agrees to perform all functions currently performed in support of the Medicaid Drug Rebate program, as prescribed by state and federal regulations." including a requirement to "Maintain an accounts receivable system to track all paid and unpaid invoices and adjustments." Further, the contract states: "The State and Federal agencies and their authorized representatives or agents will have access to the contractor's financial records, books, documents and all papers during the contract period and during the five (5) years following ..." The OIG draft report contains no findings indicating any deficiencies in ACS's accounting system, including its accounts receivable for uncollected rebates.

Accuracy and control over the accounts receivable rests with the internal controls and independent audit of ACS systems and procedures. Audits are performed routinely and audit reports have not found any major weaknesses in internal controls or discrepancies.

With regard to the statement that the receivable balance reported for June 30, 2002, on form CMS 64.9R by DHS did not correspond with the ACS receivable balance, this issue is addressed in the response to the next finding concerning **Reporting Cash Receipts**.

***Finding: Form CMS 64.9R and General Ledger Reconciliation***

The DHS did not perform a reconciliation to verify the accuracy of the uncollected rebate balances and collections reported on the Form CMS 64.9R as required by Title 45 sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations. Without a general ledger control account, routine reconciliations could not be performed.

Without routine reconciliations, the DHS did not have reasonable assurance that receivables were adequately safeguarded or that drug rebate information reported to CMS was accurate.

***Recommendation.***

Reconcile the general ledger account to the subsidiary ledgers/records and to form CMS 64.9R.

***Response:***

As noted in the response to the previous finding, the accounts receivable control account for uncollected rebate balances maintained by ACS serves as the department's detailed general ledger account for the drug rebate program. As further noted in the response to the previous finding, if DHS was to establish its own detailed general ledger account for tracking uncollected rebate balances, DHS would have to do so using information provided by ACS or duplicate each transaction handled by ACS. In effect, any reconciliation between DHS and ACS would utilize information provided from ACS records.

As described in the response to the previous finding, DHS's assurances that the rebate receivables maintained by ACS are accurate and effectively safeguarded are contained in the contract between DHS and ACS and involves continual review of ACS internal controls and procedures and audit of records. This audit found no deficiencies in ACS's accounting system or internal controls, processes or procedures with respect to receivable accounts/rebate balances.

DHS does reconcile information reported by ACS with the information DHS reports on form CMS 64.9R; but, as described below in the response to the next finding, this reconciliation process requires taking into account DHS's use of a modified accrual method to accrue revenue when it is measurable and available. However, DHS continues to pursue additional reconciliation procedures that can be implemented to enhance controls and assist in ensuring accuracy of reported receivables. The first information sharing meeting has occurred and future meetings are scheduled to develop new reconciliation and verification procedures.

***Issue: Reporting Cash Receipts***

Drug rebate collections on the Form CMS 64.9R were not reported accurately. Government Accounting and Financial Reporting standards require the States to use the modified accrual method and to accrue revenue when it is measurable and available.

There was a timing difference between DHS reporting of collections on the Form CMS 64.9R and ACS collections as recorded in subsidiary records. Specifically, DHS did not report collections by ACS for the final month of a quarter on the CMS Form 64.9R for that quarter. Rather, they reported those collections in the following quarter.

The ACS recorded receipts in the month that collections were received and applied to subsidiary accounts. Rebate checks were deposited in a DHS account managed by ACS and a single check was sent to DHS the following month for the previous month collections. For example, DHS received a check for \$2,977,860 from ACS, for June collections, dated July 10, 2002 which could have been reported on CMS Form 64.9R for the quarter ending June 30, 2002. DHS did not report June collections until the September 30, 2002 CMS Form 64.9R resulting in a \$3 million overstatement of receivables and a \$3 million understatement of collections for the June quarter.

***Recommendations:***

Reconcile quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS 64.9R.

Report rebate collections in the proper time period.

***Response:***

As stated in the finding above, DHS is required to use a modified accrual method, accruing revenue when it is measurable and available. DHS acknowledges that there is a timing difference concerning when ACS collections are recorded on the ACS ledgers and when DHS reports collections on the Form CMS 64.9R. However, such a difference is an inherent and necessary part of the accounting process whenever an intermediary such as ACS is involved in the receipt and processing of collections on behalf of DHS.

The recovery account is large and it is reasonable to expect that it would take a few days to reconcile the account; turn the money over to DHS; and post it. Therefore, timing will always be an issue. DHS contends that rebate collections are measurable and available only after ACS has reconciled the account to ensure accuracy, and the funds are deposited into the Iowa Financial Accounting System (IFAS). Consequently, DHS uses the date the rebate collections are received by DHS for purposes of reporting these collections on Form CMS 64.9R. The DHS receipt date is used for each individual report period, ensuring both consistency and accuracy over time. All collections are reported and reported only once with no duplication.

Currently, ACS reconciles the recovery account following the last day of each calendar month and issues a check to DHS early the following month. DHS then uses its receipt date for purposes of completing Form CMS 64.9R. ACS could use a different cut-off date prior to the end of each calendar month so that collections received by ACS as of the cut-off date can be reconciled and the check issued so DHS receives it before the end of the month. However, such a measure would still not address the underlying timing problem as collections received by ACS after the cut-off date each month would not be reported and issued to DHS until the next month.

Ultimately then, there simply is no practical way to get around the timing issue without sacrificing accuracy by foregoing reconciliation by ACS. The current practice is consistent with a modified accrual method; provides a clear and uniform reporting system as it relies on reconciled collections representing 3 complete calendar months each quarter; and ensures that all collections are reported accurately, and are reported only once. The regional Centers for Medicare and Medicaid Services (CMS) is fully aware of the manner in which DHS reports rebate collections and has indicated the process is acceptable.

In terms of reconciling Form CMS 64.9R with ACS's records, this can be done simply by accounting for the timing difference with respect to collections. For example, rebate collections reported by DHS on Form CMS 64.9R for the July-September quarter of 2002 would represent collections received by DHS in July, August and September 2002. To reconcile, DHS would look at ACS's records for June, July and August 2002.

***Finding: Dispute Resolution***

The DHS did not utilize State hearings to resolve disputes as required by the rebate agreement. Specifically, the rebate agreement requires that the State and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program.

The DHS did not use this state hearing mechanism, but instead, contacted manufacturers directly, and used Dispute Resolution Program (DRP) meetings for those manufacturers who attended. Because manufacturers were not required to attend DRP meetings, and there were no other sanctions provided in the regulations, there were no incentives for the manufacturers to resolve claims. The DHS did not actively pursue disputes that were not adjudicated during DRP meetings or through direct contact. Direct contact generally consisted of a notification letter and perhaps a follow-up letter.

As a result, rebates totaling nearly \$2.5 million remained uncollected dating back to January 1, 1993.

***Recommendation.***

Make use of the state's hearing mechanism to resolve disputes over 60 days.

*Response:*

While the rebate agreement between CMS and drug manufacturers contains a provision that "CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid Program," it's unclear how CMS imposes this requirement on the states. States are not a direct party to the rebate agreement and DHS is unaware of any authoritative requirement from CMS concerning the use of the state's Medicaid hearing mechanism to resolve drug rebate disputes. As previously discussed in the BACKGROUND section of this response, the drug rebate program relies largely on guidelines rather than regulatory requirements. The finding itself reinforces this deficiency by acknowledging that drug "manufacturers were not required to attend DRP meetings and there were no other sanctions provided in the regulations, there were no incentives for the manufacturers to resolve claims."

Although the report indicates that there are nearly \$2.5 million in uncollected disputed claims, it fails to indicate how many individual disputes and drug manufacturers are represented by this amount. The report also fails to acknowledge that the actual value of these claims could potentially be substantially reduced through the dispute resolution process because of provider billing errors. Further, as the report indicates, this amount has accrued over nearly a 10-year period. As noted in the BACKGROUND section of this response, DHS has collected rebates totaling over \$280 million between July 1992 and June 2002. Taken in this context, the outstanding \$2.5 million represents only a small part (less than 1%) of the drug rebate program in Iowa.

Each disputed claim represents a cumulative amount determined by multiplying the specified unit rebate amount (URA) times the number of units or doses of the drug for which the state made a payment with Medicaid funds for some specified period of time. The concern of using either a state administrative hearing mechanism or pursuing other options such as suing the drug manufacturer is that the state would be required to provide documentation of every prescription covered by the rebate being disputed. Such efforts are extremely labor intensive and divert limited staff resources from other functions that ensure services are provided, providers are paid and rebates are invoiced, collected and reported. The cost of pursuing individual disputes that cumulatively make up the \$2.5 million may in many instances exceed the rebate amount eventually collected. As noted later in the response to this issue, ACS actively pursues the top 25 labelers in Iowa and has been very successful in doing so using DRP meetings and contact letters.

DHS contends that the current provisions of both the rebate agreement and the *Dispute Resolution Guide* are insufficient to adequately address disputes and place an unreasonable burden on the states. Any attempt to authorize or require states to resolve rebate disputes through a formal hearing process must provide states flexibility in determining which disputes are cost-effective to pursue, or alternatively, place the burden on the drug manufacturers to demonstrate that the rebate amount sought by the state is incorrect. There should also be clear federal authority for an enforcement mechanism. While a state Medicaid hearing can result in a determination that a drug manufacturer owes a specified amount, there must then be some way to

compel the manufacturer to make payment or to otherwise collect the rebate. Lacking this authority, states have limited ability or options for enforcing the results of such resolution.

As described in the BACKGROUND section of this response, dispute resolutions are further complicated by the lack of any restrictions on the ability of drug manufacturers to recalculate unit rebate amounts or to dispute claims for an indefinite time. DHS encourages CMS to adopt federal regulations to address both issues.

In Section K, page 1 of the Medicaid Drug Rebate Operational Training Guide used by OIG as part of the review, *"CMS encourages States and labelers to work in partnership to resolve disputes. However, we recognize that there are disputes that cause the two parties to come to an impasse or that require technical clarification on related drug issues. CMS's DRP team is available to help move the dispute through to resolution. Several DRP national meetings are held each year, and we encourage all States and labelers with disputes to attend these meetings. ... More comprehensive information on working through the DRP process is available in the Best Practices for Dispute Resolution, which was sent to all States and labelers in 1999."*

In Section VII-24 of the Best Practices for Dispute Resolution, *"If a State and a manufacturer reach an impasse and are unable to agree on a settlement to the dispute, the State may request an administrative hearing. Requesting a hearing should be a State's last resort and should only be pursued if all other avenues have been tried and failed."*

As indicated above, there appears to be no authoritative requirement that the state use its Medicaid hearing mechanism to resolve disputes. The rebate agreement is between CMS and the drug manufacturers; states are not a party to the agreement. Even the *Dispute Resolution Guide*, while having no regulatory authority, states that "the State may request an administrative hearing", rather than "shall request." Under the current circumstances, DHS and ACS have found repeated direct contact with drug manufacturers and DRP meetings to be the best vehicles for resolving disputes in a cost-effective manner. ACS focuses its resources in resolving disputed claims to those involving the top 25 labelers. These 25 labelers represent approximately 80% of all rebate amounts as well as 80% of all disputed claims.

DHS supports CMS sponsorship of additional DRP meetings and the promulgation of regulations requiring drug manufacturers to attend these meetings. DHS also supports the development and implementation of additional regulations imposing sanctions on and/or offering incentives to drug manufacturers to cooperate in the dispute resolution process, including enforcement to collect resolved disputes. During the exit conference, the auditors suggested that DHS consider writing-off some \$547,456 in older claims. DHS is interested in exploring this suggestion; however, we are unaware of any authority allowing states to write-off claims. DHS requests confirmation that such action is allowable, and under what circumstances.

***Finding: Interest on Late, Disputed, and Unpaid Rebates***

The DHS did not have adequate procedures to accrue interest for late, disputed or unpaid rebate payments as required by Federal rules and regulations.

According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, manufacturers are required to pay interest on disputed or unpaid amounts and late rebate payments. The interest rate according to Section 1903 (d)(5) of the Social Security Act is "based on the yield of the weekly 90-day Treasury bill auction rates" during such period. Section V, paragraph (b) of the rebate agreement states:

*(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.*

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS. In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State. Finally, Governmental Accounting and Financial Reporting standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available.

The DHS did not calculate and accrue interest for late or disputed payments as required by federal regulations, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid. Moreover, they did not make significant efforts to collect from manufacturers that did not voluntarily remit interest owed.

Because the DHS did not accrue revenue as required, the drug rebate receivables were perpetually understated, and it is likely that the DHS did not receive interest owed by the manufacturers.

*Recommendation:*

Estimate and accrue interest on all overdue rebate balances.

*Response:*

As clearly stated in the finding, it is the drug manufacturer's responsibility, not the states', to calculate and pay interest for all applicable rebate invoices.

Although states are responsible for tracking collections and reporting these amounts to CMS, DHS is unaware of any authoritative requirement that the state either calculate, or recalculate, the interest amount; interest calculation is the manufacturer's responsibility.

Section I, page seven of the Medicaid Drug Rebate Operational Training Guide provides, *"If the State determines that its administrative costs to recover interest owed by a labeler exceed the interest due, the State may apply up to a \$50 tolerance per labeler to interest payments."* DHS and ACS intend to set up a mechanism to apply this \$50 tolerance.

**Finding: Interest Reporting**

The DHS did not establish procedures to report interest received as required by Federal rules and regulations, but instead, included interest as a rebate collection on the Form CMS 64.9R. According to the State Medicaid Manual, interest should be reported separately on the Form 64 summary sheet. Reporting interest revenue on Form 64.9R caused the receivables to be understated by \$6,271 for the fiscal year ending September 30, 2002.

As a result, drug rebate collections were overstated and the receivable balance was understated for that period, as were all other quarterly results that were reported using this methodology.

**Recommendation:**

Properly report interest collections on the Form CMS 64 Summary Sheet.

**Response:**

In February 2003, ACS began reporting to DHS as a separate line-item, the amount of Drug Rebate interest collected and deposited into the Recovery Account. DHS has begun reporting interest collections separately on the Form CMS 64 Summary Sheet since that time.

**Finding: Records Retention**

The DHS did not adequately retain records pertaining to the Medicaid drug rebate program as required.

Title 45 Sec. 92.42 paragraph (b)(3) of the Code of Federal Regulations requires that records for a cooperative agreement (continued or renewed quarterly) be kept three years from:

*"...the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year."*

Furthermore, the CMS "Best Practices for Dispute Resolution" states that:

*"States should maintain completed and accurate records of all checks received, unit adjustments, write-offs, resolutions, interest paid, outstanding balances, and contacts with manufacturers. The lack of adequate and accurate documentation prolongs the process of rebate payment, as well as the process of resolution of disputes.... records should be maintained indefinitely at this point."*

The DHS' current contractor, ACS, did not pursue the collection of receivables totaling \$547,456 for the period January 1, 1993 through June 30, 1997. ACS inherited responsibility for these receivables from the previous fiscal agent and ACS personnel determined that the records supporting these receivables were missing or incomplete. The missing information is required to re-start the dispute resolution process.

The records were not maintained because the DHS did not have effective policies and procedures to ensure that the contractors maintained proper records. As a result, the DHS may not have received all drug rebates due from manufacturers.

*Recommendation:*

Ensure that records are kept for an appropriate period of time.

*Response:*

As described in the BACKGROUND section of this response, DHS and ACS did experience problems in obtaining records from the previous contractor during the transition period. ACS invested an enormous amount of staff time and resources working with manufacturers to rebuild the Iowa Medicaid Drug Rebate records back to 1991; unfortunately, even this effort may not have resulted in a complete record for every single rebate transaction. ACS has since maintained complete and accurate records concerning the drug rebate program. The findings do not indicate any deficiencies in the records ACS has maintained since becoming the manager for the rebate program.

With respect to the \$547,456 in claims that occurred prior to ACS becoming the program manager, these again represent only a very small part of the total rebate program. Pursuing these claims would require additional resources that neither DHS nor ACS have available. As previously noted, DHS is requesting confirmation whether all or part of this amount may be written-off as suggested by the auditors during the exit conference.

# ACKNOWLEDGMENTS

Report Number: A-07-03-04014  
Review of the Medicaid Drug Rebate Program in Iowa

This report was prepared under the direction of James P. Aasmundstad, Regional Inspector General for Audit Services. Other principal Office of Audit Services staff that contributed include:

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